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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS
LIABILITY LITIGATION

This Document Relates to:
Linda Secrest v. Merck & Co., Inc.

Case No: 1:06-cv-06292-JFK

MDL NO. 1789
1:06-md-1789 (JFK)

**DEFENDANT MERCK SHARP & DOHME CORP.'S
MEMORANDUM IN OPPOSITION TO PLAINTIFF'S
MOTION IN LIMINE TO EXCLUDE CERTAIN EVIDENCE**

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Defendant Merck, Sharp & Dohme Corp. (“Merck”) responds to Plaintiff’s motion *in limine* as follows.

I. Plaintiff Cannot Shield The Jury From The Truth That She Blamed Her Dentist For Her History Of Infections And Osteomyelitis.

Given that Plaintiff has sued and settled with her dentist (Dr. Alexander) for \$350,000 for causing the very injuries that she now blames on Fosamax, it is no wonder that Plaintiff asks this Court to keep the settlement amount from the jury. However, Plaintiff’s motion seeks to exclude far more than that, including judicial admissions made in Plaintiff’s own pleadings in the *Alexander* case and admissions in highly relevant correspondence with Plaintiff’s own doctors in this case. Plaintiff cannot invoke Rule 403 simply because her previous admissions are against her interest in her current case against Merck.

As the Court knows from Merck’s other filings, Merck’s position in this case is that Fosamax did not cause Plaintiff to develop ONJ. Instead, Plaintiff had a long history of dental infections that eventually led to osteomyelitis of the jaw and devitalized bone. This Court has repeatedly recognized that infections, including osteomyelitis,¹ are a potential cause of ONJ. *See, e.g., In re Fosamax Prods. Liab. Litig.*, No. 06-cv-7631, 2009 WL 4042769, at *8 (S.D.N.Y. Nov. 23, 2009) (granting Merck summary judgment where plaintiff’s causation expert “did not rule out or otherwise address other possible causes for the injury to plaintiff’s jaw, such as trauma or infection”); *In re Fosamax Prods. Liab. Litig.*, No. 06-md-1789, 2011 WL 2566074, at *1 (S.D.N.Y. June 29, 2011) (noting that osteomyelitis is one of the “[r]eported alternate causes of ONJ”).

1. Osteomyelitis of the jaw is an infection in the jaw bone. *Id.*

Earlier this year, the Court granted Merck's request for an order compelling Plaintiff to produce the settlement agreement from her lawsuit against Dr. Alexander. (*See* Order, Jan. 28, 2001, ECF No. 133.) Plaintiff's only arguments in opposing Merck's request were that Merck had not made a formal discovery request for the settlement agreement (which was incorrect) and that Plaintiff was no longer in possession of the settlement agreement.² In granting Merck's request, the Court rejected those arguments. In any event, at no time did Plaintiff argue that her lawsuit against Dr. Alexander was irrelevant to her case against Merck.

Now, Plaintiff disingenuously states again and again in her motion that her lawsuit against Dr. Alexander is not relevant to the matters at issue in this case. She claims that litigation dealt solely with dental issues ("ill fitting crowns and bridges") and only with injuries arising from treatment that took place from "1999 to 2001." (Pl.'s Br. 1.) However, as Merck's expert oral surgeon Dr. Norman Betts has explained, those ill-fitting crowns, which permitted the "ingress of bacteria and infection into [Plaintiff's] hard and soft tissues" were one of the factors that precipitated Plaintiff's long history of persistent infections, pain, osteomyelitis, and ultimately ONJ. (*See* Beausoleil Decl. Ex. 4 at 9.)

Indeed, in her lawsuit against Dr. Alexander and correspondence regarding that lawsuit, Plaintiff alleged that Dr. Alexander's treatment resulted in injuries continuing through at least 2004 (the year she now claims she developed ONJ from Fosamax), and that these injuries included infections and osteomyelitis:

- In October 2001, Plaintiff wrote a letter to Dr. Alexander in which she blamed her "unrelenting discomfort" and "continuing infections," on Dr. Alexander's

2. (*See* Declaration of William J. Beausoleil ("Beausoleil Decl."), Aug. 16, 2011, Ex. 1 at 1, 3, 4; Beausoleil Decl. Ex. 2 at 14–19; Beausoleil Decl. Ex. 3 at 2, 5–6 (stating that Plaintiff's lawsuit against Dr. Alexander was relevant to the present case because it involved allegations that Alexander caused some of the same injuries at issue in the present case).)

“substandard” treatment of her. She complained further that: “I am in intractable pain, function is seriously impaired, and the ongoing infections are contributing to my anemia.” (Beausoleil Decl. Ex. 5.)

- In May 2003, Plaintiff filed a malpractice lawsuit against Dr. Alexander in Florida state court in which her written complaint alleged that she “suffered infections” in her mouth as a result of Dr. Alexander’s malpractice. (Beausoleil Decl. Ex. 6 at 2, ¶ 7, and accompanying affidavit at 1, ¶ 5.) She further alleged that her injuries from Dr. Alexander’s treatment were “permanent and continuing in nature” and that she would “suffer them for the rest of her life.” (*Id.* at 2, ¶ 7.)
- In August 2003, less than a year before the June 2004 date that Dr. Marx now claims she developed ONJ from Fosamax, Plaintiff gave a deposition in the *Alexander* case in which she testified that she was still suffering the effects of Dr. Alexander’s malpractice, and that Alexander’s malpractice resulted in “infections” in her mouth. (Beausoleil Decl. Ex. 7 at 154–59.)
- In November 2004, several months *after* she claims to have developed Fosamax-induced ONJ, Plaintiff wrote a letter to Dr. Larry Epstein, her primary care physician and now Plaintiff’s non-retained expert witness in her case against Merck. In this letter, Plaintiff asks Dr. Epstein for his assistance in “clarifying” his previous deposition testimony in the *Alexander* lawsuit and reminds Dr. Epstein that he is the person who encouraged Plaintiff to sue Dr. Alexander in the first place. Plaintiff writes that she has “no doubt” that Dr. Alexander’s treatment resulted in “infections” in her mouth that led to “osteomyelitis.” Finally, Plaintiff reminds Dr. Epstein that his exact words were “this guy began a disease process in you and you should sue the bastard and I’ll go to court with you.” (Beausoleil Decl. Ex. 8.)
- Again in November 2004, in response to Plaintiff’s request, Dr. Epstein wrote a letter to help Ms. Secrest in her case against Dr. Alexander stating, “I am firmly convinced that [Plaintiff’s] osteom[y]elitis is and was related to infection as a result of” her prior dental care. (Beausoleil Decl. Ex. 9.)

Notably, in the very month following the events listed in the last two bullets above, Plaintiff settled her suit against Dr. Alexander for \$350,000. (Beausoleil Decl. Ex. 10 at 3.) Equally notable is the fact that Plaintiff now wants to shield the jury from the fact that she has *agreed* with Merck’s contention that Dr. Alexander’s treatment caused her to develop infections and osteomyelitis. Specifically, she asks the Court to exclude from evidence the fact that she sued Dr. Alexander for those infections. For the following reasons, the Court should deny Plaintiff’s motion.

A. Federal law, not Florida law, governs the admissibility of evidence in this case.

It is well settled that “federal courts sitting in diversity apply state substantive law and federal procedural law.” *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 416 (1996). Because the admissibility of evidence is a procedural matter, state law regarding the admissibility of evidence is typically inapplicable in federal court, even in diversity jurisdiction cases. *See, e.g., Orbit One Communications, Inc. v. Numerex Corp.*, 255 F.R.D. 98, 103 (S.D.N.Y. 2008) (“The Federal Rules of Evidence typically control civil actions in federal court, regardless of subject matter jurisdiction.”); *City of New York v. Beretta U.S.A. Corp.*, 228 F.R.D. 147, 156 (E.D.N.Y. 2005) (“Federal courts will apply their own procedure and evidentiary rules in adjudicating state substantive law litigations.”).

Plaintiff notes that Florida has adopted a statute precluding the admission of the fact that a plaintiff signed “[a] release or a covenant not to sue” another “tortfeasor who may be liable for the same tort,” and that Florida courts have interpreted this statute as precluding the admission of any evidence of prior litigation against a different defendant arising from the same injury. *See* Fla. Stat. Ann. § 768.041(3); *Webb v. Priest*, 413 So.2d 43, 46 (Fla. Dist. Ct. App. 1982). However, that statute is a procedural one, not a substantive one, and therefore does not apply in the present case.

A state law addressing the admissibility of evidence is substantive only if its purpose is to affect behavior outside of the context of litigation. For example, in *Mass. Mut. Life Ins. Co. v. Brei*, 311 F.2d 463 (2d Cir. 1962), the court ruled that New York’s law precluding the admission of conversations between a plaintiff and her physician was substantive rather than procedural because that law “affects private conduct before litigation arises” and “goes to relationships established and maintained outside the area of litigation.” *Id.* at 466. State evidentiary law that

is simply aimed at efficiently resolving litigation, however, is procedural and therefore inapplicable in federal courts. *See, e.g., Sims v. Great Am. Life Ins. Co.*, 469 F.3d 870, 882-83 (10th Cir. 2006) (noting that state evidentiary law is procedural if its purpose is the “efficient resolutions of disputes”); *Barron v. Ford Motor Co.*, 965 F.2d 195, 199 (7th Cir. 1992) (Posner, J.) (noting that state evidentiary law is procedural where it is aimed at “economy in litigation”).

The purpose of Florida Statute section 768.041(3) is to facilitate the settlement of multi-defendant cases, not to preclude the use of a Plaintiff’s judicial admissions and statements against interest in one case against the same Plaintiff in another case. *See Saleeby v. Rocky Elson Constr., Inc.*, 3 So.3d 1078, 1084 (Fla. 2009) (noting that the purpose of section 768.041(3) is to “promote Florida’s public policy to encourage settlement”). In other words, the statute is aimed at the “efficient resolutions of disputes,” *Sims*, 469 F.3d at 883. There is no indication that the purpose of the statute is to influence “private conduct before litigation arises.” *Mass. Mut. Life Ins. Co.*, 311 F.2d at 466. As a result, the statute is procedural, not substantive, and therefore inapplicable to the present case. *See Taurus IP, LLC v. DaimlerChrysler Corp.*, 559 F. Supp. 2d 947, 964 (W.D. Wis. 2008) (state evidentiary law was procedural because it was aimed at “economy” in litigation rather than affecting “behavior outside of the courtroom”).

B. Under federal law, the fact that Plaintiff previously sued Dr. Alexander is highly relevant and admissible.

Plaintiff’s state court complaint against Dr. Alexander is admissible as a statement by a party opponent. *See Fed. R. Evid. 801(d)(2)* (“a party’s own statement, in either an individual or representative capacity” is admissible against that party). Indeed, the Second Circuit has stated that the law is “clear” that “pleadings constitute the admissions of a party opponent and are admissible in the case in which they were originally filed as well as in any subsequent litigation involving that party.” *United States v. McKeon*, 738 F.2d 26, 31 (2d Cir. 1984).

The fact that these statements constitute lay opinions by Plaintiff does not preclude their admission. *See* Advisory Committee Note, Fed. R. Evid. 801(d)(2) (stating that admissions are not subject to “the restrictive influences of the opinion rule and the rule requiring firsthand knowledge”); K. Broun, *McCormick on Evidence* § 256 (6th ed. 2006) (noting that “the rule limiting lay opinions” does not apply to admissions by a party opponent, and that “the prevailing view is that admissions in the form of opinions are competent”); *McKeon*, 738 F.2d at 32 (“Admissions may thus be used even though the statement was plainly self-serving when made, was not based upon the personal knowledge of the speaker and is in a form that would otherwise be inadmissible”).

Indeed, federal courts around the country have held that pleadings (including pleadings from previous lawsuits) in which a plaintiff blames her injuries on someone other than the defendant present in the case at the time of trial are admissible against the plaintiff:

- *Barnes v. Owens-Corning Fiberglass Corp.*, 201 F.3d 815, 829 (6th Cir. 2000) (holding that complaints filed by the plaintiff blaming toxic exposure injuries on non-parties to the present trial were “relevant to causation and sufficiently probative to survive Rule 403 scrutiny”);
- *Dugan v. EMS Helicopters, Inc.*, 915 F.2d 1428, 1432 (10th Cir. 1990) (noting that “where a plaintiff files a lawsuit against different defendants for the same injuries, allegations from that prior complaint are considered evidentiary admissions against interest”);
- *Williams v. Union Carbide Corp.*, 790 F.2d 552, 556 (6th Cir. 1986) (holding that “plaintiff’s belief that” another party caused his injuries, as reflected in a previous lawsuit filed by the plaintiff, was “probative” to “impeach the plaintiff’s accusation against” a different party in a subsequent lawsuit, and that “there is nothing unfair about having to explain one’s past lawsuits”);
- *Burdish v. Tex. & Pac. Ry. Co.*, 569 F.2d 320, 323–24 (5th Cir. 1978) (where plaintiff filed state court complaint alleging her injury was caused by the negligence of one party, that complaint was admissible against plaintiff in a subsequent federal lawsuit in which she blamed a different party for her injury);

- *Mason v. Texaco, Inc.*, 129 F.R.D. 542, 546 (D. Kan. 1989) (permitting product liability defendant to read into evidence plaintiff's prior pleadings in which she blamed dismissed parties for her injury);
- *Stratton v. Sacks*, 99 B.R. 686, 694 (D. Md. 1989) (where plaintiff had filed a previous lawsuit blaming damages on certain persons, that complaint was admissible in plaintiff's subsequent lawsuit seeking same damages from different persons);
- *Trexlar v. Seaboard Sys. R.R., Inc.*, 641 F. Supp. 688, 689–90 (W.D.N.C. 1986) (where plaintiff filed state court complaint alleging her injury was caused by the negligence of one party, that complaint was admissible against plaintiff in a subsequent federal lawsuit in which she blamed a different party for her injury).

In sum, it is well settled that a plaintiff's previous pleadings in which she blamed her injuries on someone else constitute statements by a party opponent that are admissible on the issue of causation. As a result, Plaintiff's motion to exclude evidence regarding her lawsuit against Dr. Alexander should be denied.

II. Plaintiff's *Daubert* Motion To Exclude Dr. Betts From Testifying About The Florida Department Of Health Disciplinary Action Against Dr. Alexander Is Untimely And, In Any Event, Without Merit.

In October 2005, Dr. Alexander admitted the allegations brought against him by the Florida Department of Health relating to his treatment of Plaintiff. Specifically, Dr. Alexander admitted that he violated the "minimum standards of performance in diagnosis and treatment" of Plaintiff by:

- treating eight of Plaintiff's teeth with no treatment plan (Pl.'s Ex. 8 at 14–15, Aug. 2, 2011, ECF No. 195-8);
- failing to perform or record a periodontal examination during any examination of Plaintiff and failing to measure and record any pockets in Plaintiff's mouth (*id.* at 15);
- failing to immediately address the dental decay present in "the majority" of Plaintiff's teeth and due to her Sjogren's Syndrome, "which tends to accelerate dental decay when that decay is left untreated" (*id.* at 15–16);

- failing to recommend “available methods of dealing with a patient’s damaged teeth and minimal teeth surface . . . to increase the potential of more of a patient’s teeth surviving” (*id.* at 16);
- failing to document Plaintiff’s “treatment progress with regular photographs to record changes in teeth and tooth structure” and failing to employ “routine x-rays and other diagnostic tools . . . throughout the entire period of treatment” (*id.* at 16–17); and
- failing to properly seat crowns with appropriate margins in Plaintiff’s mouth (*id.* at 17).

Merck should be permitted to offer testimony and evidence of the stipulated settlement with the Florida Department of Health and the admissions contained therein made by Dr. Alexander, who will almost certainly not testify at trial in this case. Plaintiff has known about Dr. Betts’ reliance on these admissions for some time and has stood silent. Any attempt to now preclude Dr. Betts from offering these opinions is clearly untimely, and Plaintiff presents no reason why the Court should now consider such an argument. And Dr. Alexander’s various admissions of substandard care are squarely relevant to the opinions that Dr. Betts will offer at trial and substantially outweigh any prejudicial effect from their use.

A. Plaintiff’s *Daubert* motion to exclude Dr. Betts from testifying about the Florida Department Of Health disciplinary action against Dr. Alexander is untimely.

Merck’s expert oral surgeon, Dr. Betts, stated in his expert report that Dr. Alexander’s “questionable dental work” predisposed Plaintiff to “infection.” As one of the bases for this opinion, Dr. Betts noted the Florida Department of Public Health’s disciplinary action against Dr. Alexander, in which the Department found that Dr. Alexander installed multiple crowns that were short of their prepared margins and that resulted in “infections.” (Beausoleil Decl. Ex. 4 at 9; Pl.’s Ex. 8 at 14, 18.)

Plaintiff now apparently wants to preclude Dr. Betts from mentioning the Florida disciplinary action against Dr. Alexander. However, her request to exclude such testimony is

untimely. *Daubert* motions to exclude or limit expert testimony were due on January 28, 2011. Indeed, on that date Plaintiff filed a *Daubert* motion to exclude several other aspects of Dr. Betts testimony, but her *Daubert* motion did not include a request that this Court preclude Dr. Betts from testifying that Dr. Alexander's care of Plaintiff contributed to Plaintiff's injury or that the Florida disciplinary action was an inappropriate basis for that opinion. Plaintiff offers no excuse for filing an untimely *Daubert* motion. Therefore, on this basis, her request to exclude Dr. Betts from mentioning the Florida disciplinary action should be denied.

B. Dr. Alexander's settlement with the Department of Health is relevant to the facts of this case, and its relevance substantially outweighs any prejudicial effect.

Because the findings are one of the bases upon which Dr. Betts has formulated his opinion, the Court has the discretion to permit Dr. Betts to talk about those findings during his direct examination. *See* Fed. R. Evid. 703 ("facts or data" relied upon by expert "that are otherwise inadmissible" may "be disclosed to the jury by the proponent of the opinion" if "the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect").

1. *The probative value of the Alexander settlement is substantial.*

Here, Plaintiff argues that Dr. Alexander's settlement with the Florida Board of Dentistry is wholly irrelevant to her case. Plaintiff is wrong. Dr. Alexander's treatment of Plaintiff is absolutely relevant to the issue of causation—whether Fosamax or Plaintiff's long-standing medical and dental complications caused her alleged injuries—which is the subject of Dr. Betts' testimony in this case.

Plaintiff summarily claims that Dr. Alexander's treatment is irrelevant to her injury because it involved "purely dental (i.e., crowns) procedures." As Merck's expert Dr. Norman Betts has opined, the "purely" dental work for which Dr. Alexander was disciplined, along with

certain pre-existing conditions, predisposed to Plaintiff to “ingress of bacteria and infection into her hard and soft tissues through severe dental caries, periodontal disease and associated periapical infections.” (Beausoleil Decl. Ex. 4 at 9.) This resulted in a “progressive infection,” which persisted throughout and beyond his course of treatment (*id.* at 10), including during several attempted and invasive implant procedures and bone grafts (*id.* at 23; Beausoleil Decl. Ex. 11 at 35–36; Beausoleil Decl. Ex. 12; Beausoleil Decl. Ex. 13 (noting “major reconstruction of her lower mandible with cadaver bone graft.”)). During this time, Plaintiff experienced “local bone destruction” (Beausoleil Decl. Ex. 11 at 36), as well as fistulas and chronic infection (Beausoleil Decl. Ex. 4 at 10–12), which Dr. Betts has opined existed in her teeth, soft tissue, *and* jaw bone (Beausoleil Decl. Ex. 14 at 95:7 – 96:21). Further, Ms. Secrest’s “premature loss of teeth due to Dr. Alexander’s poor dental work made her subsequent restorative situation much more challenging requiring more extensive and invasive procedures.” (Beausoleil Decl. Ex. 4 at 9.)

For these reasons, Plaintiff’s assertion that Dr. Alexander’s treatment cannot be relevant to her injury because it was “purely dental” must fail. Dr. Alexander’s admission that he was “guilty of incompetence or negligence by failing to meet the minimum standards of performance in diagnosis and treatment” of Plaintiff is certainly relevant to the issue of whether his treatment is related to the injuries at issue in this case. (Pl.’s Ex. 8 at 18.)

2. *There is little to no prejudice from use of the Alexander settlement at trial.*

With regard to possible prejudice that may be suffered, Plaintiff makes several arguments in support of her position that prejudice would result from evidence of the Department of Health’s Administrative Complaint as a government report under Rule 803(8)(C). Yet none of the logic in Plaintiff’s arguments applies to Dr. Alexander’s *admission* of the allegations

contained in the Complaint. Indeed, Plaintiff has offered no good reason why this evidence would cause her prejudice.

Initially, Plaintiff argues that Dr. Alexander's stipulated admissions would be cumulative because Merck's experts can rely on Plaintiff's dental records at trial to opine that Dr. Alexander provided substandard care. This argument misses the important point that no evidence contained in Plaintiff's medical records is as probative of the care provided by Dr. Alexander as are his own admissions.

Plaintiff next argues that juries are likely to give undue weight to administrative findings in government reports. However, administrative findings were never made by the Department of Health; instead, as Plaintiff notes, the Administrative Complaint contains factual allegations and legal conclusions. At issue here is Dr. Alexander's *admissions* of those allegations, and any concern that the jury would give undue weight to the Department's Complaint is obviated by these admissions.

Finally, Plaintiff cites one inapposite case in support of its argument that, if admitted into evidence, the stipulation would "undermine the exclusive province of the jury." *United States v. McDonald*, 688 F.2d 224, 230 (4th Cir. 1982). In that case, the Court of Appeals noted that investigative reports that contain *credibility determinations* tend to undermine the jury's role of assessing the credibility of evidence. The evidence Merck seeks to introduce at trial is not an investigative report, let alone one that contains a credibility determination. Indeed, Plaintiff has failed to offer any explanation how Dr. Alexander's stipulation would undermine the jury's role.³

3. In *McDonald*, the court upheld the exclusion of a probable cause report because it had no relevance to the ultimate question—"whether defendant committed the crimes charged." *Id.* The court added that "its admission would have tended to perplex" the jury because it "would have distracted the jury's attention from its task of ascertaining guilt or innocence." *Id.* In this case, because evidence that Dr. Alexander administered

(Footnote continued on next page)

Because Plaintiff did not timely move to prevent Dr. Betts from relying on Dr. Alexander's admission of the allegations contained in the administrative complaint filed against him, and because the probative value of such evidence significantly outweighs any potential prejudicial effect of such evidence, evidence and argument on the subject should not be excluded at trial.

III. Merck Will Not Argue That Doctors "Vote" On The Efficacy And Safety Of Fosamax With "Their Prescription Pads"; Therefore Plaintiff's Argument Is Moot.

Plaintiff seeks to exclude argument that practicing physicians have "voted" on the safety and efficacy of Fosamax "with their prescription pads." Plaintiff singles out a single statement from the transcript of a three-week trial in support of her argument that Merck intends "to speak for every physician in the world prescribing, for any and every, patient population."⁴ (Pl.'s Br. 25.) Plaintiff's contention appears, at best, to be a logical stretch. In any event, as Merck does not intend to make this specific statement in the *Secrest* trial, which is very clearly the subject of Plaintiff's motion, this motion is moot.

However, Merck does wish to make clear that it does not concede that any argument or evidence regarding the popularity of Fosamax should be excluded at trial, nor that it opens the door to "evidence of [Merck's alleged] massive marketing onslaught." (*Id.* at 24.) This Court has repeatedly held that Plaintiff should not be permitted to introduce evidence as to the marketing or promotion of Fosamax unless it is directly related to her use of the medication.

(Footnote continued from prior page)

admittedly substandard care speaks squarely to the issue of causation, the *McDonald* ruling is highly distinguishable.

4. Plaintiff also asserts that the analysis of risk-benefit in this case should be conducted solely with reference to Plaintiff, and not the larger patient population. (*See* Pl.'s Br. 24–25.) As the Court is aware, Merck respectfully objects to this reading of Florida law, which the Court has certified for interlocutory appeal to, and which will be fully briefed before, the Second Circuit Court of Appeals.

(*See* Beausoleil Decl. Ex. 15 at 494:4-7; Beausoleil Decl. Ex. 16 at 57:18 – 58:1; Beausoleil Decl. Ex. 17 at 35:2-3.) As Merck has argued in support of its *in limine* motion, neither Plaintiff nor her prescribing physician has indicated that she or he relied upon any specific marketing materials; accordingly, the Court should exclude all such evidence as it did in *Boles*. (*See* Def.’s Br. 15–16; Beausoleil Decl. Ex. 15 at 494:4-7 (“The plaintiff may not introduce evidence of marketing or promotion materials because she has not established that she or her prescribing physician . . . were exposed to any specific materials.”).)

IV. Merck Does Not Oppose Plaintiff’s Request To Exclude Evidence Regarding HugeSettlements.com.

Plaintiff seeks to exclude reference to the appearance of Dr. Suzanne Parisian’s name on the website HugeSettlements.com. As the basis for this motion appears to be one that goes to weight and credibility—that Dr. Parisian allegedly had no involvement with listing herself on the site and took active steps to remove herself from the list—Merck would expect that an experienced witness like Dr. Parisian could very capably defend herself on cross-examination should this website ever come up again at trial. However, because Merck does not intend to raise this issue during the *Secrest* trial and will instead focus its efforts on cross-examination of Dr. Parisian elsewhere, the motion is unopposed.

V. Merck Does Not Oppose Plaintiff’s Request To Exclude Testimony Regarding Frank Secrest’s Health Or Death; Any Limitation On Such Evidence Must Be Mutual.

Merck agrees that no reference should be made by either party to Frank Secrest’s recent illnesses or death, including the fact that Ms. Secrest has recently been widowed. His claim against Merck having been dismissed, any such evidence would be irrelevant to the issues on trial. Therefore, the motion is unopposed.

VI. Merck Generally Opposes Plaintiff's Vague Motion About Arguing The Absence Of Excluded Evidence And Respectfully Submits That The Court Should Reserve Its Ruling Until An Evidentiary Dispute Arises.

In this section of her brief, Plaintiff asks the Court to “exclude argument about the absence of . . . excluded evidence.” (Pl.’s Br. 35.) Citing only to plaintiff’s overruled objection in *Graves* (which has already been the subject of a full briefing to the Second Circuit), Plaintiff’s vague request essentially asks that the parties follow the rules of evidence at trial, suggesting that one side has not. To that end, Merck has and will continue to abide by the Court’s rulings in previous bellwether cases; to the extent Plaintiff or her counsel disagrees, her counsel is free to raise contemporaneous objections at trial.

VII. Topics Of The Court’s Prior Rulings

A. Merck’s proposed testimony is fully consistent with the Supreme Court’s holding in *Wyeth v. Levine*, and Plaintiff’s request for exclusion does not relate to any evidence Merck intends to present.

As with prior motions *in limine* made by other plaintiffs in this MDL, Plaintiff dedicates several pages of her *in limine* brief to a discussion of the Supreme Court’s 2009 *Wyeth v. Levine* decision, and concludes with a request that the Court “enter [an] order precluding Merck from arguing or offering testimony that it *could not* amend the Fosamax label to include warnings or precautions concerning risks without FDA approval.” (Pl.’s Br. 32 (emphasis added).)⁵ Previous plaintiffs have presented nearly identical arguments prior to the *Boles I* and *Maley* trials.

5. Plaintiff asserts that this line of argument—which Merck has never made in prior trials and does not intend to make in this case—“would convert this case into a trial about the FDA’s conduct rather than Merck’s failure to provide adequate warnings in its label.” (Pl.’s Br. 2.) Merck agrees that while the role of FDA cannot be ignored, putting the FDA’s conduct on trial serves only to obfuscate the issues and expects Plaintiff in this trial to eschew the kinds of irrelevant and prejudicial arguments previous plaintiffs have advanced, which include how the FDA is funded, its competency in approving drugs, and its allegedly “incestuous” relationship with the pharmaceutical industry. (Beausoleil Decl. Ex. 18 at 1669:10-24, 1680:13-16, 1681:16-25, 1682:2-3.)

As in the preceding MDL trials, Merck does not intend to present evidence that Merck *could not*, under the law, have changed the Fosamax label without prior FDA approval. It is entirely proper and in accord with the *Levine* holding for Merck to take the position that utilizing the CBE provision was not the only course of action and was not the most reasonable and prudent course of action in this case. (Beausoleil Decl. Ex. 19 at 42:3-10 (“As I ruled in *Boles*, Merck is precluded from arguing, or introducing evidence in support of, the proposition that it could not add a warning to or otherwise strengthen Fosamax’s label without FDA approval. This ruling does not preclude Merck from arguing, or introducing evidence in support of, the proposition that seeking FDA approval before changing a label can be an appropriate or reasonable approach.”); Beausoleil Decl. Ex. 20 at 473:16-20.)

The Court should apply its holding in those cases again here.

B. Merck does not oppose Plaintiff’s request to exclude proactive testimony regarding personal and family members’ use of Fosamax; any limitation on such evidence must be mutual.

Plaintiff argues that Merck’s witnesses should be precluded from discussing whether they or their family members took Fosamax because such evidence is irrelevant to the issues of this case. Plaintiff simply repeats the same arguments made in prior MDL trials and ignores the fact that Merck has made no attempt to introduce such evidence in the three Fosamax trials. Merck requests that the Court apply its prior rulings on this issue to the present case:

Merck may not introduce evidence that its employees and their family members used Fosamax. . . . However, should the plaintiff challenge the credibility of a witness who states that his or her belief that Fosamax is safe, then Merck could rehabilitate that witness through evidence that the witness personally used Fosamax . . . if it provide[s] to plaintiff prior to trial a list of its witnesses who have used Fosamax.

(Beausoleil Decl. Ex. 21 at 44:2-11.)

C. Plaintiff's request to exclude "good character" evidence is overly broad and should not be granted.

Previous plaintiffs have made nearly identical motions to exclude "good character" evidence in both the first *Boles* trial and the *Maley* trial. Just as the Court has held when considering the motions in these prior cases, the ruling Plaintiff seeks remains demonstrably overbroad. Merck does not dispute that an attempt to offer evidence of wholly unrelated good acts—*e.g.*, Merck's investment of research, medicines, and funds to eliminate river blindness in Africa—would be contrary to Merck's own efforts to limit the focus of the trial to the truly relevant issues. However, Merck should be allowed, as in past trials, to offer evidence that it manufactures drugs to treat and cure diseases, and for Merck employees to testify about their professional history at Merck. Merck therefore requests that the Court again hold that "evidence that it manufactures drugs and that the purpose of their manufacture and their sale is to treat and to seek to cure diseases" is admissible in this case. (Beausoleil Decl. Ex. 22 at 476:5-7.)

D. The risks associated with Plaintiff's concurrent medication are relevant to this case.

Plaintiff also seeks to exclude any argument or evidence of Plaintiff's use of other prescription drugs for the purpose of establishing "that either she or her physician were willing to accept the risks of a non-osteonecrosis of the jaw condition for a medication other than Fosamax." (Pl.'s Br. 35.) Again, Merck has no intention of arguing that Plaintiff's history of taking other medications make her a "risk taker." However, Merck should not be precluded from introducing evidence of risks associated with other medications Plaintiff was taking in "questioning whether Fosamax caused, contributed to or exacerbated plaintiff's ONJ and for the purpose of determining damages." (Beausoleil Decl. Ex. 23 at 478:3-6.)

E. Plaintiff's motion seeking to preclude alleged "fear-mongering" should be denied because it is vague and seeks to preclude Merck from describing the disease Fosamax is designed to treat and prevent.

Plaintiff alleges that Merck "'stepp[ed] into the jury box'" during the second *Boles* trial and "engaged in fear-mongering." (Pl.'s Br. 35.) Plaintiff offers only two examples of alleged "fear-mongering" by Merck, both occurring during the testimony of Merck expert Dr. John Bilezikian. The first example Plaintiff cites is Dr. Bilezikian's simple recital of facts and statistics on the consequences and dangers of hip fractures. (*Id.*) The second is testimony offered in direct response to the question of whether Dr. Bilezikian considered osteoporosis to be a dangerous disease. (*Id.* at 36–37.) Plaintiff does not (indeed, cannot) allege that any of the testimony offered by Dr. Bilezikian was untruthful. This testimony was highly relevant to Plaintiff's claim of design defect and was not improper or otherwise prejudicial. Plaintiff cannot characterize Merck's presentation of evidence as "fear-mongering" simply because that evidence, which consists of non-graphic statistics, is unpleasant or inconsistent with her theory of the case. Plaintiff has failed to demonstrate how either example violated any statutes, case law, or rules of evidence.

Just as in prior trials, this Court should continue to allow Merck to provide the jury with background about osteoporosis and osteoporotic fractures, including a description of what they are and to what larger health consequences they can lead. Past plaintiffs in this MDL have routinely attempted to downplay the significance of osteoporosis, and Merck should continue to be permitted to provide the jury relevant evidence describing the severity of osteoporotic fractures.

Plaintiff also contends that Merck should be precluded from making the argument that a jury verdict would result in Fosamax being "pull[ed] . . . from the shelves." (*Id.* at 37.) But that is exactly what Plaintiff seeks through her design defect claims. A plaintiff asserting a design

defect claim is necessarily arguing that the product should be redesigned or taken off of the market. *See* D. Owen, M. Madden & M. Davis, *Madden & Owen on Products Liability* § 8:1 (3d ed. 2000) (“a judicial declaration that the design of a particular product on trial is ‘defective’ condemns the entire product line”); *Young v. Pollock Eng’g Grp., Inc.*, 428 F.3d 786, 789 (8th Cir. 2005) (to prevail on a design defect claim, plaintiff must generally show either the product should be redesigned or that it should be removed from the market); *Tobin v. Atra Pharm. Prods., Inc.*, 993 F.2d 528, 536 (6th Cir. 1993) (test for defective design is whether “an ordinarily prudent manufacturer, being fully aware of the risks, would have placed the product on the market”). Plaintiff has not offered any evidence of an alternative design for Fosamax, so by alleging that Fosamax is defectively designed she is necessarily arguing that Fosamax should be taken off of the market. There is nothing “improper and misleading” about arguing that Plaintiff’s design defect claims directly put at issue the question whether Fosamax should be made available as a prescribing choice for doctors.

F. Plaintiff’s meritless attempt to deflect attention from her Counsel’s improper behavior in the *Boles II* trial should be denied.

Plaintiff’s last request barely merits a response. As the Court recognized at the end of the *Boles II* trial, the argument Plaintiff presents in her eleventh *in limine* request is nothing more than “an effort by the [P]laintiff to throw some more tomatoes against the wall in the hope that some of it splatters back against [Merck]. And also that, in some way, [Plaintiff’s] tomato will obliterate Mr. Douglas’ objects that he threw against the wall.” (Beausoleil Decl. Ex. 24 at 1748:23 – 1749:2.)

To the extent the Court seriously considers Plaintiff’s last ground, Merck agrees that neither party should imply that the Court has any particular view of the evidence (which is not what Merck’s counsel did in the second *Boles* trial).

